Exploring pregnant women and professional perspectives on use and adherence to oral iron during pregnancy

Overview

We would like to invite you to take part in a research study looking at your views on anaemia during pregnancy and taking iron supplements.

WHY ARE WE DOING THIS?

- We want to hear your views about a health condition that can occur during pregnancy named anaemia, and any experience of this you may have had.
- We would like to understand what encourages and helps pregnant women to take iron supplements throughout their pregnancy, and if there are any factors that make taking these supplements challenging.
- We hope to use this information to develop strategies to better support women to take iron supplements during pregnancy.

WHAT WOULD I NEED TO DO?

- You would be asked to take part in a one-to-one conversation with a trained researcher, lasting approximately 45 minutes.
- This could be done either by telephone, audio/video conference call platforms or in person, depending on what works well for you.
- The researcher will ask you about your views and/or experience of anaemia and oral iron supplements during pregnancy.
- There are no right or wrong answers and we are interested in hearing a wide range of perspectives.

WHO CAN GET INVOLVED?

- Adult pregnant woman with and without anaemia, who are and are not taking oral iron supplements.

Further study information is provided below, as well as contact details for scheduling the conversation if you are interested in taking part.

Participant Information Sheet

Exploring pregnant women and professional perspectives on use and adherence to oral iron during pregnancy.

Chief Investigator: Prof Simon Stanworth

Lead Investigator: Dr Fabiana Lorencatto

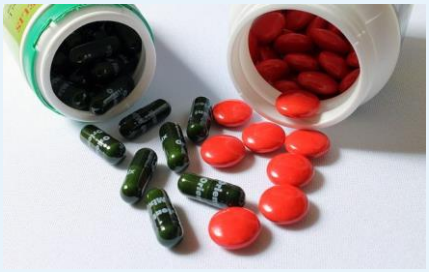
INVITATION TO TAKE PART IN A RESEARCH STUDY

We would like to invite you to take part in our research study as we want to hear your views and opinions. Before you decide if you want to take part, we would like to tell you why the research is being done, and what you can expect if you take part. Please read what we have to say carefully. Please feel free to talk to others about the study if you wish and take as much time as you like to decide. If you have any questions for the researchers, their contact details are provided in a later section of this information sheet – please do feel free to get in touch with them.

WHAT IS THE PURPOSE OF THE STUDY?

This study is the first part of our research programme called Primary prevention of maternal Anaemia to avoid preterm Delivery and other Adverse outcomes, or PANDA for short. In this part of the study, we want to hear what pregnant women, such as yourself, think about anaemia during pregnancy and use of iron tablets. Some of you may have had experience of having anaemia or taking iron tablets and we want to hear about this too. This will help us develop strategies to better support women to take iron tablets throughout pregnancy.

Some women develop anaemia during pregnancy. Anaemia is when red cells are reduced in the blood. At present, we do not have a good understanding of all health problems caused by anaemia in pregnancy. Anaemia can also be challenging for healthcare professionals to diagnose and treat.



Currently, we treat women with iron supplements (i.e. tablets containing iron that can potentially help increase low levels of iron in the blood) if they develop anaemia during pregnancy. However, we know that it can sometimes be challenging to take these medications consistently. There are also some arguments for giving iron to women before they develop anaemia (i.e. for prevention of anaemia rather than treatment once it has happened). We need to better understand if this is the case and what the issues are in relation to taking iron throughout pregnancy.

WHY HAVE I BEEN INVITED TO TAKE PART?

You are being invited to take part because you are a pregnant woman.

We would like to talk to pregnant women from a range of backgrounds, who can speak English well enough to have a structured discussion with us, so that we can explore all perspectives including:

1. Women of different ages (but you must be at least 18 years old or older).
2. Women who have had different numbers of previous pregnancies.
3. Women from different ethnic groups.
4. Women with and without anaemia .
5. Women who are taking iron or other supplements and those who are not.

DO I HAVE TO TAKE PART IN THE STUDY?

This decision is entirely yours. If you do decide to take part, you are free to withdraw at any time and without giving a reason. If you choose not to participate, this will not affect the care you receive from your own doctors and midwives.

WHAT WILL HAPPEN IF I DO TAKE PART?

There are two main parts to this study if you take part.

Part 1:

We would like to make sure that we are talking to a diverse range of pregnant women. So, we will ask you to fill in a short questionnaire about yourself asking the following:

- your age
- number of pregnancies and children
- ethnicity
- relationship status
- region of the UK you live in
- education.

Part 2:

We would like to talk to you about anaemia during pregnancy and taking iron and other supplements. One of our trained researchers will have this conversation with you (which we call a research interview). This could last for approximately 45 minutes and will be a one-to-one conversation. We can arrange to talk to you at a place and time that is suitable and convenient for you. If you prefer, this discussion can be done over the telephone or via audio/video conference call platforms. We want to hear your opinions and so there are no right or wrong answers to the questions we ask you.

The researcher will ask you to give consent in writing in the first instance (either by printing, signing and scanning and emailing the form or posting the form, or by electronically adding your signature). However, if this is not possible you will be asked to give verbal consent, before the conversation. If consent is taken verbally, this will be audio-recorded and transcribed for record keeping. The audio-recording will be deleted once a check, written transcript is produced. This consent is necessary for us to ensure that you understand the purpose of your involvement, your rights as a participant, and that you agree to the conditions of your participation. With your permission, the conversation will be recorded, and a transcript of your responses will be produced. If you would like, you can be sent a copy of your transcript to review and you will be able to clarify or remove any information. The transcript of the conversation will be analysed by the research team at University College London (UCL). The transcript will be fully anonymised so that no one can be identified.

WHAT ARE THE POSSIBLE RISKS OF TAKING PART?

We do not anticipate that there are any risks associated with your participation, but you have the right to stop the conversation or withdraw from the research at any time. The conversation can be done over the phone or via audio/video conference call platforms if that is preferable or easier for you.

WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART?

Your views will help us develop more useful and relevant strategies to support women to take iron tablets as recommended by their healthcare team in future. We hope this will lead to improved prevention and management of anaemia during pregnancy. You might also find it helpful to talk about your views and experiences during pregnancy.

WILL TAKING PART IN THE STUDY BE KEPT CONFIDENTIAL?

All the information that is collected about you during the study will be kept strictly confidential and secure in line with the law as set out in the General Data Protection Regulation (GDPR) and will be anonymised.

NHS Blood and Transplant (NHSBT) is the sponsor for this study and will act as the data controller. This means that we are responsible for looking after your information and using it properly. The sponsor is collaborating with researchers from UCL for this study.

The audio recording of the conversation (and verbal consent if applicable) and data collected from you will be held by the researchers at UCL, stored on a secure, password protected computer or in a locked filing cabinet (if hard copy data), in a locked office accessed through a swipe locked building. Only members of the research team will have access to your audio-recording. An external, UCL approved and GDPR compliant transcription service will transcribe the audio-recorded interviews. A confidentiality agreement will be in place with the transcription service to make sure they maintain confidentiality and security of the information. Once a written, anonymised transcript is produced all audio recordings will be deleted. These data about you (e.g. your transcript) will be kept in this secure location for 5

years after completing the study. After this time, it will be destroyed. Paper consent forms will be destroyed within 12 months of completing the study.

Those who will be able to view the interview transcript will be limited to members of the research team. We will write our reports in a way that no-one can work out that you took part in the study. Any information that is used from the recorded conversations (for example in published articles), including direct quotes, will be fully anonymised (meaning that names of people or places and any other identifying information will be removed).

In the unlikely event that you disclose anything which we feel puts you or anyone else at risk, confidentiality may need to be broken. We will first discuss with the chief investigator (consultant haematologist), and if required report this to relevant teams, organisations and authorities where appropriate. You will be kept informed at every stage.

HOW WILL WE USE INFORMATION ABOUT YOU?

We want to make sure that we are talking to a diverse range of pregnant women and so will use the information collected in the questionnaire about yourself to help us to do this. Data collected about you during the conversation will be used for this study.

We will make sure that all the data collected about you has no link to your name. We will assign the data collected about you an anonymous ID number. Data from the questionnaires and from the recorded conversation will be stored separately. As described above, we will keep all information about you safe and secure and will not share this information more widely beyond the research team.

WHAT ARE YOUR CHOICES ABOUT HOW YOUR INFORMATION IS USED?

Before, during and after the recorded conversation, you can stop being part of the study at any time, without giving a reason. You can also choose to skip over any questions you do not wish to answer, and to answer in as much or as little detail as you would like. Once all of the data has been transcribed and anonymised, the data will be used in the research and withdrawal will not be possible.

WHERE CAN YOU FIND OUT MORE ABOUT HOW YOUR INFORMATION IS USED?

You can find out more about how we use your information in the following places:

- https://www.nhsbt.nhs.uk/privacy/
- by contacting Katrina Smith who is Data Protection Officer and Head of Information Governance for NHSBT DPO@nhsbt.nhs.uk

WHAT IF THERE IS A PROBLEM?

If at any stage, you have concerns about the study or the way it has been carried out you should tell either the researcher who is conducting the study or the study lead or Chief Investigator (see contact details below). You can also talk to your midwife or doctor. You can also talk to the Patient Advice and Liaison Service (PALS) in the hospital:

- The Royal Free London: Tel: 020 7472 6446 or 0207472 6447 | https://www.royalfree.nhs.uk/contact-us/patient-advice-and-liaison-service-pals/
- The Royal Wolverhampton: rwh-tr.pals@nhs.net | Tel: 01902 695368 (or 695362) /07880 601085 | https://www.royalwolverhampton.nhs.uk/patients-and-visitors/patient-experience-team/
- Oxford University Hospital NHS Foundation Trust: PALS@ouh.nhs.uk | https://www.ouh.nhs.uk/patient-guide/feedback/documents/here-to-help.pdf
- Sunderland Royal Hospital: pals@cntw.nhs.uk | Tel: 0191 566 7074

If you remain unhappy and wish to complain formally you can do this through the NHS complaints procedure. Ask anyone in the clinic and you will be provided with an appropriate information leaflet.

Taking part in the study does not alter your legal rights in any way if you have grounds for legal action.

WHAT WILL HAPPEN TO THE RESULTS OF THE RESEARCH STUDY?

At the end of the study, we will analyse results and publish in medical journals and present in other reports and presentations. However, you will not be identified in these publications and reports. If you would like a copy of the results, please tell the researcher interviewing you.

WHO IS ORGANISING THE RESEARCH?

The research is funded by the National Institute for Health Research (NIHR), sponsored by NHS Blood and Transplant (NHSBT) and carried out by a research team from University College London, University of Oxford, Nottingham University, The Royal Wolverhampton NHS Trust, Imperial College London, Oxford University Hospitals NHS Foundation Trust, and the Royal Free NHS Foundation Trust.

WHO HAS REVIEWED THE STUDY?

All research is looked at by an independent group of people, called a Research Ethics Committee, to protect your safety, rights, wellbeing and dignity. This study has been reviewed by the Health Research Authority NHS Research Ethics committee (Wales REC1; Reference: XX) and the NHSBT Research & Development Department team.

WHAT HAPPENS NOW?

If you are interested in taking part in this study, please inform your care team who handed this information sheet to you or contact the researcher directly (contact details below). The researcher will then arrange an agreed time and place to have the interview. The researcher will go through the study information with you and give you the opportunity to ask questions. If you are still happy to proceed, the researcher will ask you to provide consent either in writing or verbally.

WHO SHOULD I CONTACT FOR FURTHER INFORMATION?

If at any time during the study, you have questions or concerns regarding the study you can contact the Research Team:

- Dr Elise Crayton (Research Fellow): e.crayton@ucl.ac.uk | Tel: 020 7679 5947
- Dr Fabiana Lorencatto (Study Lead): f.lorencatto@ucl.ac.uk
- Prof Simon Stanworth (Chief Investigator): simon.stanworth@nhsbt.nhs.uk | Tel: 01865381037; NHS Blood and Transplant, John Radcliffe Hospital, Oxford OX3 9BQ

Thank you for taking the time to consider taking part in this study.